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Different Lifestyle Interventions in Adults From Underserved Communities

The FAMILIA Trial

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ABSTRACT

BACKGROUND The current trends of unhealthy lifestyle behaviors in underserved communities are disturbing. Thus, effective health promotion strategies constitute an unmet need.

OBJECTIVES The purpose of this study was to assess the impact of 2 different lifestyle interventions on parents/caregivers of children attending preschools in a socioeconomically disadvantaged community.

METHODS The FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) study is a cluster-randomized trial involving 15 Head Start preschools in Harlem, New York. Schools, and their children's parents/caregivers, were randomized to receive either an "individual-focused" or "peer-to-peer–based" lifestyle intervention program for 12 months or control. The primary outcome was the change from baseline to 12 months in a composite health score related to blood pressure, exercise, weight, alimentation, and tobacco (Fuster-BEWAT Score [FBS]), ranging from 0 to 15 (ideal health = 15). To assess the sustainability of the intervention, this study evaluated the change of FBS at 24 months. Main pre-specified secondary outcomes included changes in FBS subcomponents and the effect of the knowledge of presence of atherosclerosis as assessed by bilateral carotid/femoral vascular ultrasound. Mixed-effects models were used to test for intervention effects.

RESULTS A total of 635 parents/caregivers were enrolled: mean age 38 ± 11 years, 83% women, 57% Hispanic/Latino, 31% African American, and a baseline FBS of 9.3 ± 2.4 points. The mean within-group change in FBS from baseline to 12 months was ∼0.20 points in all groups, with no overall between-group differences. However, high-adherence participants to the intervention exhibited a greater change in FBS than their low-adherence counterparts: 0.30 points (95% confidence interval: 0.03 to 0.57; p = 0.027) versus 0.00 points (95% confidence interval: −0.43 to 0.43; p = 1.0), respectively. Furthermore, the knowledge by the participant of the presence of atherosclerosis significantly boosted the intervention effects. Similar results were sustained at 24 months.

CONCLUSIONS Although overall significant differences were not observed between intervention and control groups, the FAMILIA trial highlights that high adherence rates to lifestyle interventions may improve health outcomes. It also suggests a potential contributory role of the presentation of atherosclerosis pictures, providing helpful information to improve future lifestyle interventions in adults. (J Am Coll Cardiol 2020;75:42–56) © 2020 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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Cardiovascular (CV) health disparities among different racial, ethnic, and socioeconomic groups persist in the United States (1). Differences in CV disease burden are broadly attributable to modifiable risk exposures such as hypertension, high cholesterol levels, smoking, dietary risks, obesity, and low physical activity (2). The Committee of the National Academies of Sciences, Engineering, and Medicine recently identified promoting CV health as one of the 4 priorities areas for action (3). Primary prevention guidelines also emphasize that the most important way to prevent disease is to promote a healthy lifestyle throughout life (4); however, changing our lifestyle behaviors as adults is challenging. Therefore, there is a need to create approaches that may result in positive, measurable changes in prevalent poor health metrics (5). In particular, the sustainability of health promotion interventions remains largely unknown. Proven success strategies could be potentially implemented at a wider scale to fulfill the goal of reducing the burden of modifiable risk factors significantly at a population level (6).

With the aim of promoting health in a socioeconomically disadvantaged community using a family-centered approach, in 2015 we launched the FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) trial (7). Children attending Harlem public preschools and their parents/caregivers were recruited and randomized to parallel health promotion intervention programs or to control. We recently demonstrated that children aged 3 to 5 years receiving a 4-month preschool-based educational intervention to promote health improved their knowledge, attitude, and habit scores toward a healthy lifestyle (8). The present paper reports the peak effects (primary endpoint) and sustained effects (sustainability) of the health promotion interventions delivered among the parents/caregivers participating in the FAMILIA trial.

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METHODS

STUDY DESIGN, SETTING, AND PARTICIPANTS. The design and rationale of the FAMILIA study has been previously published (7). Briefly, the study is a parallel-group cluster-randomized controlled trial targeting children aged 3 to 5 years and their parents/caregivers from 15 public preschools in Harlem, New York City. Participating schools are part of the Head Start program (U.S. Department of Health and Human Services) that provides comprehensive services to low-income children and their families. School staff were also considered "caregivers" because they are with the children up to 50 h weekly. During the course of the study, schools participating in FAMILIA agreed not to take part in any other major structured health intervention program aside from the usual curriculum.

ABBREVIATIONS AND ACRONYMS

FBS = Fuster-BEWAT Score

IIIP = intensive individual intervention program

PPPI = peer-to-peer program intervention

Schools and parents/caregivers were recruited between October 2015 through May 2017, and were randomized in a 3:2 ratio (3 intervention/2 control) with their assignment aligned to the assignment for the child (8). Those in the "intervention" group were then assigned to 1 of 2 interventions in a 1:2 ratio, thus accounting for disparate cluster sizes. The first intervention was the "Intensive Individual Intervention Program (IIIP)" consisting of 8 to 12 individual counseling sessions and a personal activity monitoring device as a motivational agent. The second intervention was the "Peer-To-Peer Program Intervention (PPPI)," consisting of monthly group meetings of participants to help everyone in the group collectively improve their CV risk factor profiles. The intervention program continued for 12 months, and participants were advised to participate in a minimum of 8 sessions.

As main follow-up assessments, parents/caregivers were scheduled to be evaluated at baseline (prior to the intervention), at approximately 12 months (immediate post-intervention, peak effect) and at approximately 24 months (12 months post-intervention, sustainability). Informed written consent was required from all participants. The Icahn School of Medicine at Mount Sinai Institutional Review Board approved the study (HS#: 14-01054), which was conducted in accordance with institutional and federal guidelines involving human subjects research. The study is registered in ClinicalTrials.gov (NCT02481401).

INTERVENTION. The description of the intervention adheres to the TIDieR (Template for Intervention Description and Replication) guidelines (9). More

research and innovation programme under the Marie Skłodowska-Curie grant agreement No 707642. Dr. Bansilal is an employee of Bayer US. Dr. Kovacic has received honoraria less than $5,000 from Medtronic. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. George A. Mensah, MD, served as Guest Associate Editor for this paper. P.K. Shah, MD, served as Guest Editor-in-Chief for this paper.

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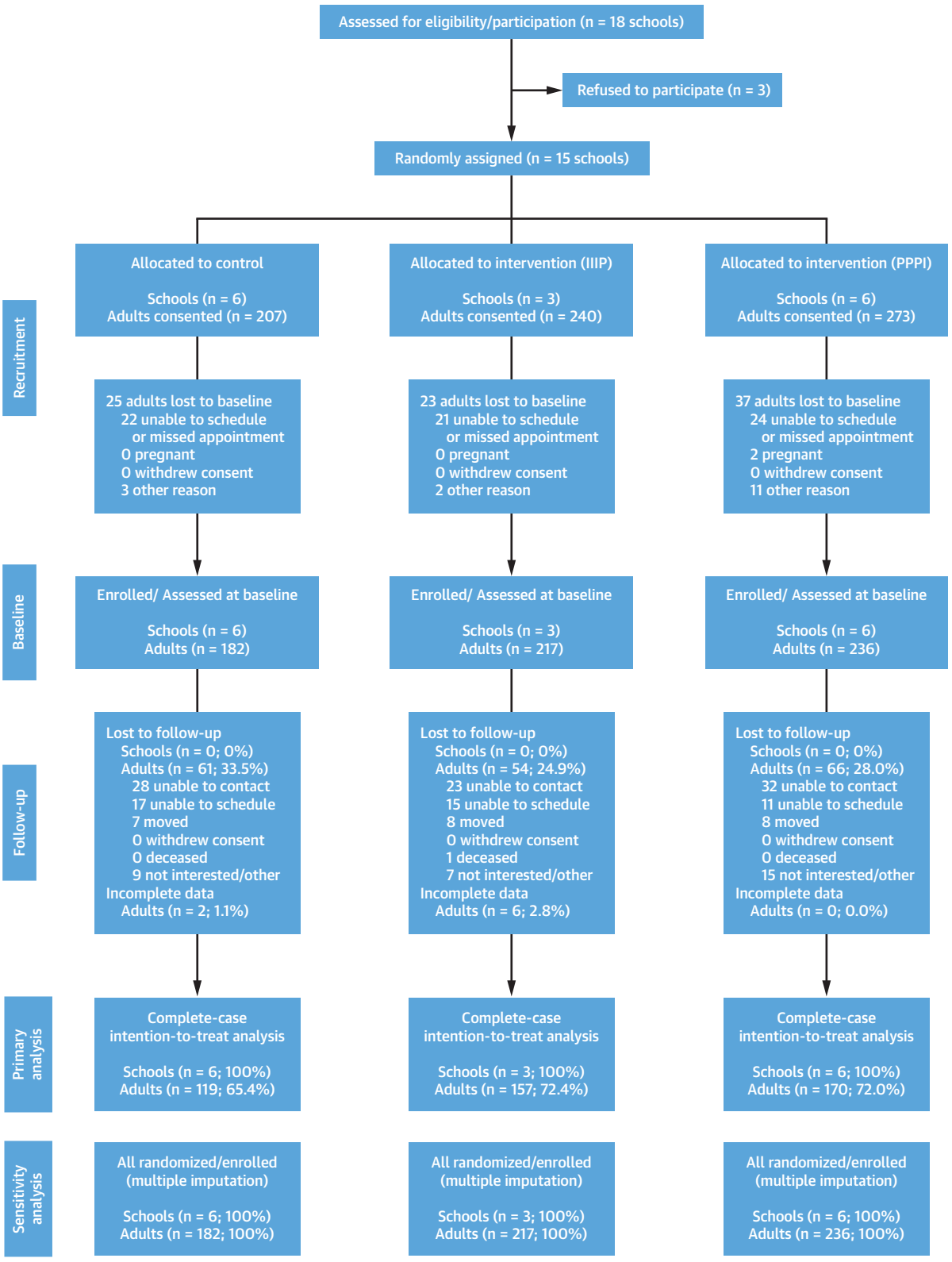
FIGURE 1 **The FAMILIA Study Flow Diagram**



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details about the intervention can be found in the Online Appendix and Online Tables 1 to 3.

Intensive individual intervention program. The IIIP comprised of 1-on-1 counseling sessions with a trained lifestyle coach. Lifestyle coaches were assigned to each of the participants and met them at an event at their children's school where they gave the Lifestyle Coaching Manual to the participants. The participants used the Lifestyle Coaching Manual to discuss the session topics pertaining to CV health over the course of the intervention. Personal activity monitoring devices (Garmin Vivofit 2 and 3, Garmin Ltd., Olathe, Kansas) was given to the participants to motivate them and to improve their activity level. The 8 coaching sessions were held once every 3 to 4 weeks, lasting approximately 45 min during the first 8 months. An additional 4 complimentary sessions were offered to the participants over the following 4 months for a total intervention duration of approximately 12 months.

Peer-to-peer program intervention. The PPPI group meetings occurred at the participant children's preschools, lasting approximately 12 months. After the 2 first sessions, the participants selected peer leaders and coleaders who accepted their role on a voluntary basis. These peer leaders and coleaders received a full day (6-h long) leadership training provided by the scientific team member of FAMILIA. The coleaders were trained so they could step-up and carry out the responsibility of a leader if the leader was not available to lead the scheduled session during the intervention. At the peer leader-led group meetings, the participants shared their own experiences, problems, and knowledge associated with health habits; evaluated changes; and offered mutual support. The 45-min sessions were held every 3 to 4 weeks and lasted for approximately 12 months.

The FAMILIA research team trained and provided regular support to the lifestyle coaches of IIIP and the peer leaders and coleaders of the PPPI during the course of the intervention. An incentive structure was established for the participants based on their session attendance with their lifestyle coaches and the group meetings.

Control group. Parents and caregivers randomized to the control arm did not receive any structured program for the first 4 months of the study. This coincided with the children not receiving any educational intervention program. After 4 months, coinciding with the crossover of the children's intervention, the control adult participants received relevant components of the health-based curriculum activities the children completed in the classroom, including newsletters with poems, arts and crafts activities, or home routines for the children related to healthy lifestyles. A detailed description of the child intervention was published elsewhere (8). Additionally, we provided informational and educational sessions on summer safety, dental hygiene, foot health, financial management, and tax advice on a quarterly basis.

Materials provided during the assessments. When participants came to the study assessments, they all received an individualized counseling session to discuss their results (e.g., weight, waist and hip circumferences, blood pressure, body mass index, lipid profile, vascular ultrasound) irrespective of their study arm allocation. They also received a representative printed picture of their carotid and/or femoral vessels, and handouts with information about weight control; guidance on interpreting results for their levels of glucose, cholesterol, and blood pressure; and tips about portion control (Online Appendix). All questionnaires and brochures were available in English and Spanish, and health counselors were fluent in both languages to accommodate participant language preferences.

PRIMARY OUTCOME: CHANGE IN OVERALL FUSTER-BEWAT SCORE. The primary outcome was the difference between groups in the change from baseline of a composite health score related to Blood pressure, Exercise, Weight (body mass index), Alimentation (fruit and vegetable consumption), and Tobacco (smoking habit) (Fuster-BEWAT Score [FBS]) at the completion of the 12-month intervention. A final 24-month assessment was performed to evaluate the sustainability of the impact of the 2 lifestyle interventions on FBS approximately 12 months after the intervention program ended. The overall score ranges from 0 (poor health) to 15 (ideal CV health), and it is derived from the sum of individual components of the score (0 to 3 points each). The details for the

FIGURE 1 Continued

Recruitment of schools and parents/caregivers, and completeness of baseline and 12-month follow-up measures, according to the guidelines in the CONSORT 2010 statement for the reporting of cluster randomized trials. Four participants are not reflected in the consort diagram: 2 participants in the PPPI-Peer group withdrew their consent and requested all of their data to be eliminated; and signed consent documents were not found for 1 participant in the PPPI-Peer group and 1 participant in the control group. IIIP = intensive individual intervention program; PPPI = peer-to-peer program intervention.

TABLE 1 Baseline Characteristics of Enrolled Schools and Adults in the FAMILIA Study

	Overall	Control	Intervention (IIIP-Individual)	Intervention (PPPI-Peer)
Schools				
No. of schools	15	6	3	6
Adults/school	42.3 ± 32.3	30.3 ± 16.7	72.3 ± 52.5	39.3 ± 28.7
Parents/caregivers				
Adults	635	182	217	236
Age, yrs	37.8 ± 11.3	38.9 ± 11.4	37.7 ± 11.4	37.1 ± 11.0
Female	524 (82.5)	152 (83.5)	175 (80.7)	197 (83.5)
Race/ethnicity				
Non-Hispanic black	197 (31.0)	70 (38.5)	39 (18.0)	88 (37.3)
Hispanic/Latino	359 (56.5)	80 (44.0)	163 (75.1)	116 (49.2)
Other/multiracial	79 (12.5)	32 (17.5)	15 (6.9)	32 (13.6)
Born outside United States	305 (48.0)	83 (45.6)	128 (59.0)	94 (39.8)
School staff	159 (25.0)	44 (24.2)	52 (24.0)	63 (26.7)
Annual household income				
<$25,000	281 (44.3)	78 (42.9)	106 (48.9)	97 (41.1)
$25,000-$50,000	164 (25.8)	51 (28.0)	45 (20.7)	68 (28.8)
>$50,000	63 (9.9)	20 (11.0)	13 (6.0)	30 (12.7)
Unknown	127 (20.0)	33 (18.1)	53 (24.4)	41 (17.4)
Highest level of education completed				
Secondary school or lower	183 (28.8)	41 (22.5)	85 (39.2)	57 (24.2)
High school	299 (47.1)	85 (46.7)	96 (44.2)	118 (50.0)
College/university/postgraduate	140 (22.1)	49 (26.9)	34 (15.7)	57 (24.2)
Unknown	13 (2.1)	7 (3.9)	2 (0.9)	4 (1.7)
Fuster-BEWAT score				
FBS overall (range 0–15)	9.3 ± 2.4	9.3 ± 2.6	9.4 ± 2.3	9.2 ± 2.4
B: Blood pressure (range 0–3)	2.2 ± 1.1	2.2 ± 1.1	2.3 ± 1.0	2.1 ± 1.1
E: Exercise (range 0–3)	1.9 ± 1.2	1.9 ± 1.2	2.0 ± 1.2	1.9 ± 1.1
W: Weight (range 0–3)	1.0 ± 1.1	1.1 ± 1.2	0.9 ± 1.1	1.0 ± 1.2
A: Alimentation (range 0–3)	1.4 ± 0.7	1.4 ± 0.8	1.5 ± 0.7	1.4 ± 0.7
T: Tobacco (range 0–3)	2.7 ± 0.7	2.7 ± 0.7	2.8 ± 0.6	2.7 ± 0.7
Vascular ultrasound				
Absence of atherosclerosis	468 (73.7)	123 (67.6)	178 (82.0)	167 (70.8)
Evidence of atherosclerosis	47 (7.4)	19 (10.4)	11 (5.1)	17 (7.2)
Not performed/not analyzable	120 (18.9)	40 (22.0)	28 (12.9)	52 (22.0)

Values are n, mean ± SD, or n (%). Adults' race/ethnicity was self-identified.

FAMILIA = Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health; FBS = Fuster-BEWAT score; IIIP = intensive individual intervention program; PPPI = peer-to-peer program intervention.

calculation of the FBS at baseline and follow-up assessments, alongside the inverse association of the FBS with the presence and extent of subclinical atherosclerosis, have been previously published (10,11). Overall, FBS was calculated for all participants with data available for measuring at least 4 of the 5 individual components of the score. For those participants with 1 individual component missing (<10%), the corresponding variable was imputed using the calculated average of the remaining 4 components of the given subject.

SECONDARY OUTCOMES: CHANGES IN FBS SUBCOMPONENTS AND SUBGROUP ANALYSIS. As secondary outcomes, the changes in the individual components of the FBS and the impact of the intervention on the overall FBS change in different subgroups were evaluated. Variables for subgroup analysis included the following: age (<40 years vs. ≥40 years), sex, self-identified race/ethnicity (non-Hispanic black, Hispanic/Latino, other/multiracial), baseline FBS (tertiles), place of birth (United States vs. outside of the United States), school staff (yes/no), self-reported annual household income (<$25,000; $25,000 to $50,000; >$50,000), self-reported highest level of education (secondary school or lower, high school, college/university/postgraduate), and the results of the baseline 3-dimensional carotid/femoral vascular ultrasound performed (evidence of atherosclerosis at any location evaluated vs. absence of atherosclerosis). The

TABLE 2 Change From Baseline in Overall Fuster-BEWAT Score and Components Among Parents/Caregivers in the FAMILIA Trial at 12 Months (Primary Endpoint)

		Within-Group Differences			Between-Group Difference	
	Score Range	Control	Intervention (IIIP-Individual)	Intervention (PPPI-Peer)	Control vs. Individual	Control vs. Peer
FBS overall	0–15	0.20 (−0.17 to 0.58)	0.20 (−0.17 to 0.57)	0.20 (−0.12 to 0.53)	−0.01 (−0.53 to 0.52)	0.00 (−0.50 to 0.49)
B: Blood pressure	0–3	0.09 (−0.08 to 0.26)	0.12 (−0.06 to 0.29)	0.11 (−0.04 to 0.26)	0.02 (−0.22 to 0.27)	0.02 (−0.21 to 0.25)
E: Exercise	0–3	0.17 (−0.02 to 0.36)	0.21 (0.05 to 0.37)	0.07 (−0.08 to 0.23)	0.04 (−0.21 to 0.29)	−0.09 (−0.34 to 0.15)
W: Weight	0–3	−0.06 (−0.19 to 0.07)	−0.14 (−0.26 to −0.03)	−0.01 (−0.12 to 0.10)	−0.08 (−0.26 to 0.09)	0.04 (−0.13 to 0.22)
A: Alimentation	0–3	0.01 (−0.15 to 0.16)	0.01 (−0.16 to 0.19)	0.01 (−0.14 to 0.15)	0.01 (−0.23 to 0.24)	0.00 (−0.21 to 0.21)
T: Tobacco	0–3	0.01 (−0.09 to 0.11)	0.03 (−0.06 to 0.12)	0.03 (−0.06 to 0.11)	0.02 (−0.11 to 0.15)	0.02 (−0.11 to 0.14)

Values are marginal mean differences and 95% confidence intervals (CI) as derived from linear mixed-effects models, unless otherwise indicated. Fixed effects were the corresponding baseline score and treatment group, while schools and families were handled as random effects.

Abbreviations as in Table 1.

methodology used for data collection alongside the ultrasound imaging protocol are described in the Online Appendix.

STATISTICAL ANALYSIS. All study data were first collected on paper, and then entered into a REDCap (Research Electronic Data Capture) database hosted at the Icahn School of Medicine at Mount Sinai, New York. Continuous variables are reported as mean ± SD, whereas discrete variables are reported as frequencies (%), unless otherwise specified. Multilevel linear mixed-effects models that account for the hierarchical cluster randomized design were used to test for the adjusted intervention effect (change in FBS). Fixed effects were the corresponding baseline FBS (as a continuous variable) and treatment group. Schools and families were handled as random effects. The same linear mixed models were applied for the analysis of the change in the subcomponents of the FBS. Interaction models were also fitted to identify possible age, sex, race/ethnicity, baseline FBS, place of birth, school staff, household income, education level, and vascular ultrasound results by treatment effects for the main outcome variable (overall FBS).

To assess a potential dose-response effect of the intervention, differences in FBS between participants receiving <50% of the program sessions (<4 sessions, low-adherence group) versus those receiving ≥50% of the program sessions (≥4 sessions, high-adherence group) were explored by the use of similar linear mixed-effects models (10). Data about adherence to the intervention were based on number of sessions attended and were collected at the individual level.

Every attempt was made to follow all enrolled participants irrespective of allocation or withdrawal from treatment. All participants were included in the analysis in the groups to which they were randomized. A complete-case intention-to-treat analysis was performed as the main analysis. Under the assumption of missing at random, multiple imputation using multivariate normal distribution was performed to include all randomized enrolled participants as sensitivity analysis. For subgroup analyses, missing values (if any) on variables used to create subgroups were not imputed; instead, pairwise deletion was performed. Details on sample size and power calculations and multiple imputation procedures carried out can be found in the Online Methods. Statistical significance was set at a p value <0.05, except in the case of the interaction analyses, in which statistical significance was set at a p value <0.10 (12). Because of

TABLE 3 Change From Baseline in Overall Fuster-BEWAT Score and Components Among Parents/Caregivers in the FAMILIA Trial at 24 Months (Sustainability)

		Within-Group Differences			Between-Group Difference	
	Score Range	Control	Intervention (IIIP-Individual)	Intervention (PPPI-Peer)	Control vs. Individual	Control vs. Peer
FBS overall	0–15	0.11 (−0.26 to 0.48)	0.22 (−0.08 to 0.53)	−0.19 (−0.50 to 0.13)	0.11 (−0.36 to 0.59)	−0.30 (−0.78 to 0.19)
B: Blood pressure	0–3	0.14 (0.00 to 0.28)	0.19 (0.07 to 0.31)	0.02 (−0.10 to 0.14)	0.05 (−0.13 to 0.24)	−0.12 (−0.31 to 0.07)
E: Exercise	0–3	0.07 (−0.14 to 0.29)	0.10 (−0.08 to 0.27)	0.02 (−0.16 to 0.20)	0.03 (−0.25 to 0.30)	−0.05 (−0.33 to 0.23)
W: Weight	0–3	0.02 (−0.13 to 0.16)	−0.10 (−0.22 to 0.03)	−0.10 (−0.23 to 0.03)	−0.11 (−0.31 to 0.08)	−0.12 (−0.31 to 0.08)
A: Alimentation	0–3	−0.08 (−0.20 to 0.04)	0.00 (−0.10 to 0.10)	−0.06 (−0.16 to 0.05)	0.08 (−0.08 to 0.23)	0.02 (−0.14 to 0.18)
T: Tobacco	0–3	0.03 (−0.06 to 0.12)	0.03 (−0.05 to 0.10)	−0.03 (−0.11 to 0.04)	−0.01 (−0.12 to 0.11)	−0.07 (−0.18 to 0.05)

Values are marginal mean differences and 95% confidence intervals (CIs) as derived from linear mixed-effects models, unless otherwise indicated. Fixed effects were the corresponding baseline score and treatment group, while schools and families were handled as random effects.

Abbreviations as in Table 1.

the a priori defined primary hypothesis and the exploratory nature of secondary analyses, results were not adjusted for multiplicity (13). All analyses were performed using STATA version 15 (StataCorp, College Station, Texas).

RESULTS

PARTICIPANT FLOW DIAGRAM AND BASELINE CHARACTERISTICS. The study enrolled 15 schools of which 9 were randomized to intervention groups (3 schools to the IIIP and 6 schools to PPPI) and 6 to the control condition, totaling 635 adults enrolled and assessed at baseline. After a median follow-up of 17 and 27 months, ~30% and ~33% of participants were lost to follow-up or had incomplete data, respectively. Therefore, 446 and 424 adults were included in the main analysis (complete-case intention-to-treat analysis) of the primary outcome (**Figure 1**) and sustainability outcome (Online Figure 1) of the study, respectively. No school withdrew from the trial during the study period, and no adverse events were reported.

Table 1 contains a summary of the collected baseline information at the school and individual levels. In summary, no significant differences were found between control and intervention groups at baseline, with the exception of a higher proportion of Hispanic/Latino patients and of participants born outside the United States in the intensive individual intervention group. Baseline information for those participants lost to follow-up or with incomplete data and for remaining participants included in the primary outcome analysis, either in the intervention groups or control, are presented in Online Table 4.

PRIMARY OUTCOME: CHANGE IN FBS AT 12 MONTHS (PEAK EFFECT). Baseline overall FBS were 9.3 ± 2.6, 9.4 ± 2.3, and 9.2 ± 2.4 in the control, IIIP-Individual, and PPPI-Peer groups, respectively. The mean within-group change from baseline at 12-month assessment in the overall FBS was approximately 0.20 points in all groups (**Table 2**). The average absolute differences in overall FBS were −0.01 points (95% confidence interval [CI]: −0.53 to 0.52; p = 0.978) between control and IIIP-Individual groups, and 0.00 points (95% CI: −0.50 to 0.49; p = 0.988) between control and PPPI-Peer groups. No significant differences were observed in any of the FBS components between groups. Overall results were similar when including all randomized enrolled participants (n = 635) after multiple imputation (data not shown).

In the IIIP-Individual group, 69% of participants (n = 149 of all 217 randomized) and 85% of participants (n = 133 of all 157 included in the complete-case intention-to-treat analysis at 12 months) attended ≥4 of scheduled sessions (high-adherence group). In the PPPI-Peer group, 50% of participants (n = 119 of all 236 randomized) and 65% (n = 111 of all 170 included in the complete-case intention-to-treat analysis at 12 months) attended ≥4 scheduled sessions. Overall, high-adherence participants exhibited a greater change in the overall FBS at 12 months than their low-adherence counterparts: 0.00 points (95% CI: −0.43 to 0.43; p = 1.0) in the low-adherence groups versus 0.30 points (95% CI: 0.03 to 0.57; p = 0.027) in the high-adherence groups; however, this difference between groups was not statistically significant (p = 0.225). Online Table 5 details the changes and differential changes in the low- and high-adherence groups in each of the intervention arms at 12 months.

SUSTAINABILITY: CHANGE IN FBS AT 24 MONTHS. The mean within-group changes from baseline at 24-month assessment in the overall FBS were 0.11, 0.22, and −0.19 points in control, IIIP-Individual, and PPPI-Peer groups, respectively, with no overall between-group differences (**Table 3**). Overall results were similar when including all randomized enrolled participants (n = 635) after multiple imputation (data not shown).

In the IIIP-Individual group, 81% of participants (n = 130 of all 161 included in the complete-case intention-to-treat analysis at 24 months) attended ≥4 scheduled sessions (high-adherence group). In the PPPI-Peer group, 66% (n = 101 of all 152 included in the complete-case intention-to-treat analysis at 24 months) attended ≥4 scheduled sessions. Overall, high-adherence participants exhibited a greater change in the overall FBS at 24 months than their low-adherence counterparts: −0.40 points (95% CI: −0.82 to 0.02; p = 0.065) in the low-adherence groups versus 0.16 points (95% CI: −0.09 to 0.42; p = 0.208) in the high-adherence groups, and this difference was statistically significant (p = 0.025). Online Table 6 details the changes and differential changes in the low- and high-adherence groups in each of the intervention arms at 24 months.

DETERMINANTS OF THE INTERVENTION EFFECTS. A breakdown of the mean differences (intervention vs. control) in the change of overall FBS at 12 months according to variables of interest is shown in **Figure 2**, whereas mean changes in each of the intervention groups are shown in Online Figure 2. This stratified analysis revealed significant interactions of the effect of the intervention with baseline overall FBS, place of

birth, and the results of vascular ultrasound. Participants starting from a lower baseline score, who were born outside of the United States and with evidence of atherosclerosis benefited more from the intervention. A trend suggesting larger benefits among school staff participants and higher self-reported annual household income (>$50,000) was also observed; however, these interactions did not reach statistical significance.

A breakdown of the mean differences (intervention vs. control) in the change of overall FBS at 24 months according to variables of interest is shown in **Figure 3**, while mean changes in each of the intervention groups are shown in Online Figure 3. This stratified analysis revealed significant interactions of the effect of both intervention groups with the results of vascular ultrasound and the condition of the individual in regards to being part of the school staff or not. Participants with evidence of atherosclerosis and school staff benefited more from the intervention. A trend suggesting larger benefits among participants 40 years of age or older, those who were born outside of the United States, and those with a higher self-reported annual household income (>$50,000) and education level was observed; however, these interactions were not statistically significant.

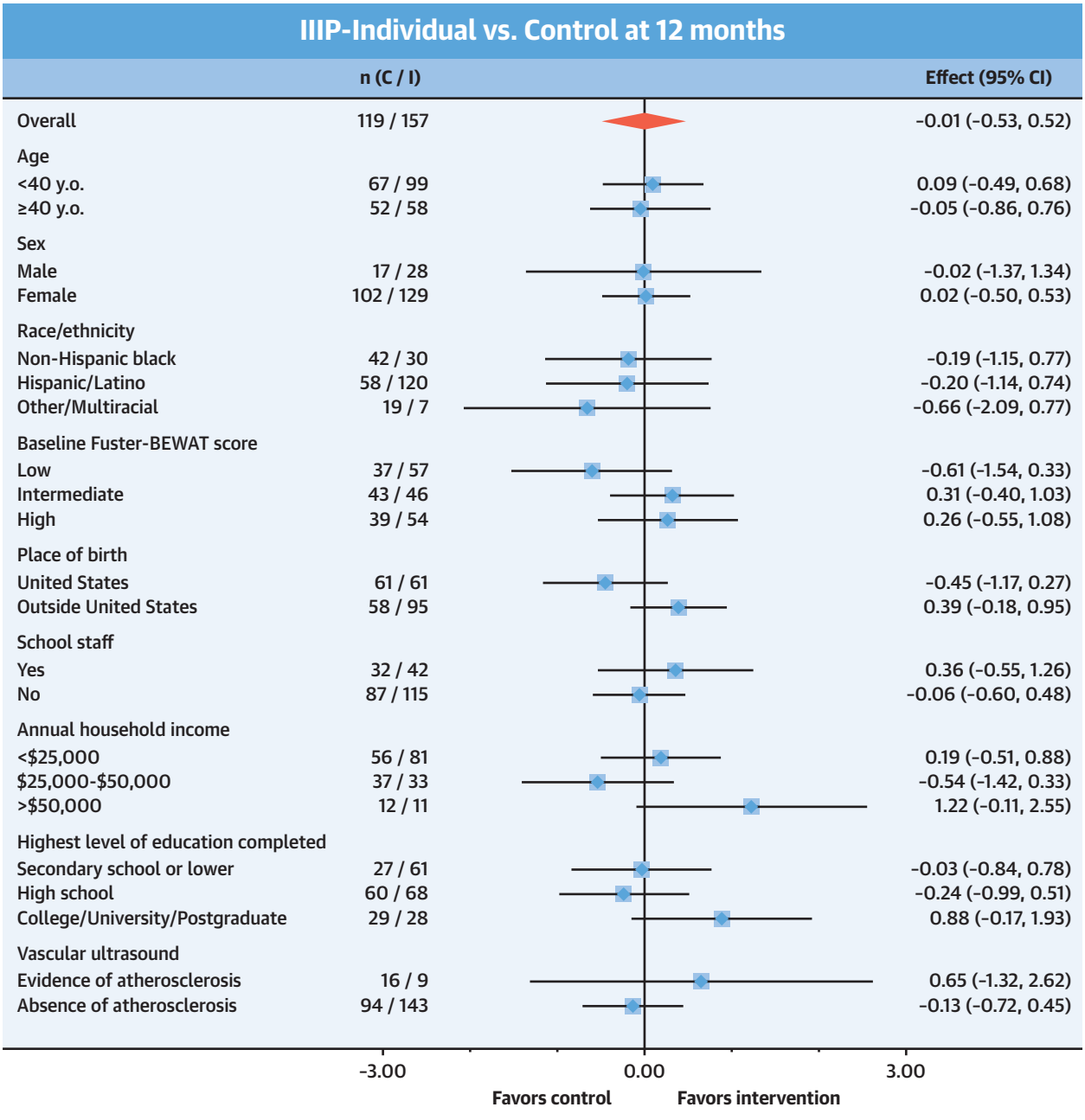
DISCUSSION

Among preschool children's parents/caregivers from an urban multiethnic community, neither an intensive individual intervention program nor a peer-to-peer program intervention delivered over the course of 12 months demonstrated a significant impact on simple health metrics compared with control subjects. The overall lack of intervention effects was seen both at immediate post-intervention and at approximately 1 year after the end of the intervention, suggesting that there were no delayed results of the intervention. However, a dose-response intervention effect was observed; those individuals attending ≥50% of the intervention program demonstrated healthier changes than their low-adherence counterparts at both timepoints evaluated. The identification and understanding of ultrasound-based images of atherosclerosis by the participant consistently boosted the intervention effects. Furthermore, we identified subgroups of participants in whom lifestyle interventions could have a greater effect. All of this information may be useful to tailor future health promotion programs in adults (**Central Illustration**).

REASONS FOR A LACK OF OVERALL INTERVENTION EFFECTS IN THE FAMILIA TRIAL. Although evidence on hard, longer-term CV outcomes resulting from lifestyle interventions is needed (14), health promotion programs using counseling and education aimed at behavior change might be effective when targeted to individuals with CV risk factors, such as type 2 diabetes or hypertension. In contrast, they may have limited use in general populations (15). The FAMILIA trial stems from prior comprehensive school-based (the SI! Program) (16–19) and peer group-based (the Fifty-Fifty Program) (10) lifestyle interventions conducted in Spain and Colombia. The Fifty-Fifty Program in Spain targeted adults 25 to 50 years of age with at least 1 CV risk factor and showed a significant improvement in the same composite FBS using a similar peer-to-peer intervention strategy, as compared with control subjects. Beyond the complexity of changing health-related behaviors (20), several factors may have decreased the ability to generate larger intervention effects in the FAMILIA trial.

First, the present study enrolled a relatively young and healthy population. Thus, the mean initial FBS was ~20% higher in the FAMILIA adult population than in the Fifty-Fifty trial (higher score indicating better health), making it more challenging to demonstrate a significant change. This finding was mostly due to healthier scores observed in the subcomponents of blood pressure and exercise among participants enrolled in the FAMILIA trial. Second, the control group received relevant health promotion messages over the course of the study. This included up to 5 counseling sessions to discuss their health and vascular ultrasound results that were offered at the end of study assessments. In addition, control parents/caregivers received relevant components of the health-based curriculum activities the children completed in the classroom. The fact that FBS in the control group increased similarly as in the intervention groups at 12 months (by ~0.20 points) supports the notion that health status knowledge and awareness might serve as triggers for actual behavior change (21). Third, the overall intervention adherence was modest, and this could have decreased the overall intervention effects. A dose-response relationship was observed, consistently with prior studies (8,10). Factors that affect intervention fidelity in health promotion programs warrants further research. Fourth, contamination in the form of shared intervention messages or products between individuals in the community cannot be excluded because the relatively small area in which the trial was conducted (i.e., Harlem neighborhood). Finally, social determinants may play an important role on intervention effects. The FAMILIA trial enrolled

FIGURE 2 **Subgroup Analysis of the Differential Changes in Overall FBS at 12 Months Between Control and Intervention Groups**



Forest plot representing mean differences (95% confidence interval [CI]) in the overall Fuster-BEWAT Score (FBS) changes at 12-month assessment between parents/caregivers in the intervention groups (IIIP-Individual, PPPI-Peer) and control groups, after stratified linear mixed-effects models by selected variables. Fixed effects were the corresponding baseline score and treatment group, while schools and families were handled as random effects. For baseline FBS subgroup analysis, the score was categorized in tertiles (low, intermediate, high) and continuous baseline score was not included in the model. C = control; I = intervention; IIIP = intensive individual intervention program; PPPI = peer-to-peer program intervention.

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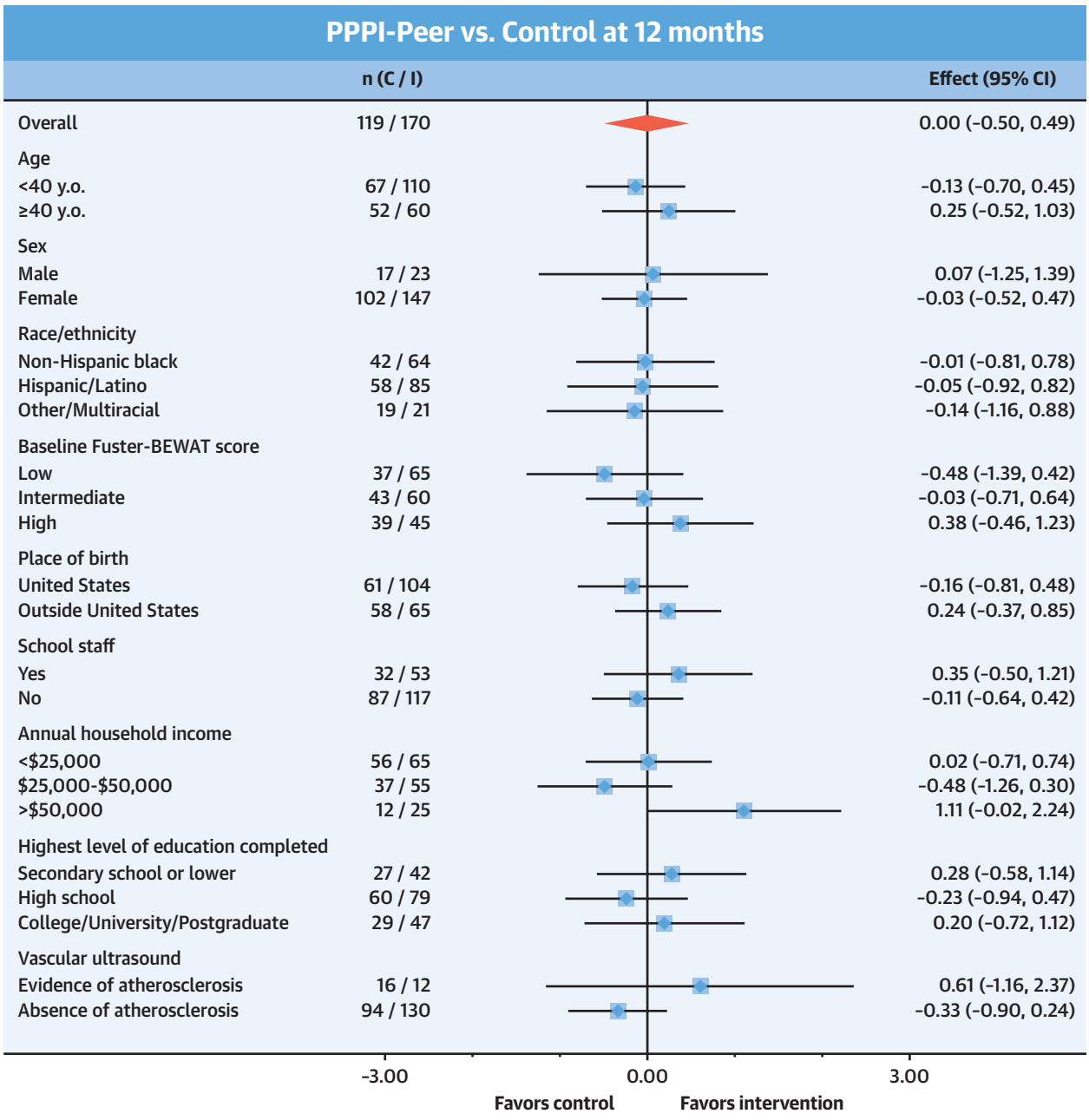
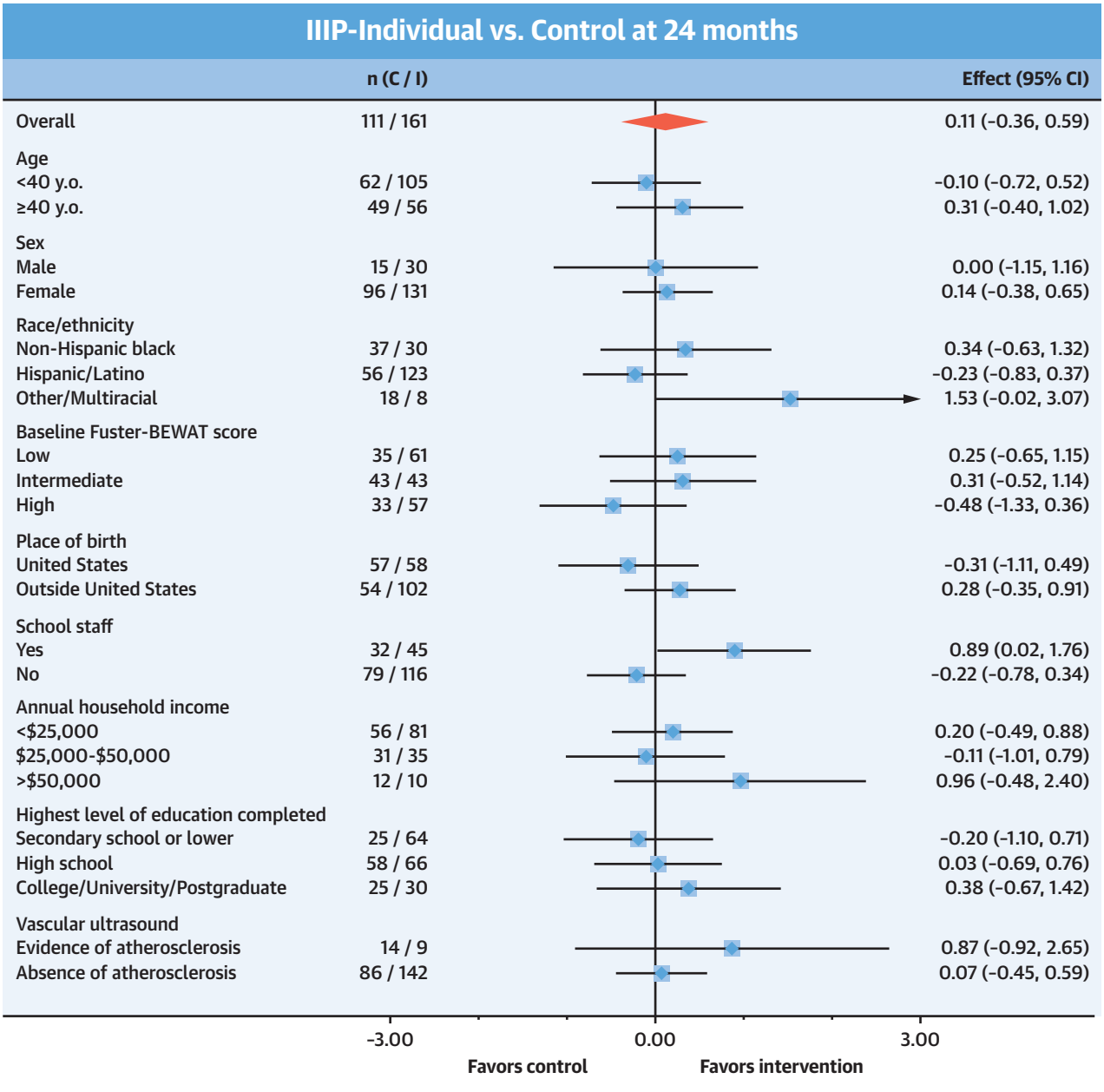
FIGURE 2 Continued



relatively homogenous low-income families. Assuming intervention effectively reached the parents/caregivers participating in the trial, low-income populations still frequently face food insecurity issues (22). Furthermore, environmental variables such as availability of affordable sport facilities and neighborhood safety may also affect the participation in physical activities (23).

DETERMINANTS OF INTERVENTION EFFECTS. A breakdown of the effect of the intervention suggested larger effects in some specific subgroups. The most consistent finding was the association of the knowledge and awareness of the presence of atherosclerosis as assessed by 3-dimensional vascular ultrasound with a higher intervention effect at both timepoints evaluated. This is consistent with the results of a

FIGURE 3 Subgroup Analysis of the Differential Changes in Overall FBS at 24 Months Between Control and Intervention Groups



Forest plot representing mean differences (95% confidence interval) in the overall FBS changes at 24-month assessment between parents/caregivers in the intervention groups (IIIP-Individual, PPPI-Peer) and control groups, after stratified linear mixed-effects models by selected variables (as in Figure 2). Abbreviations as in Figure 2.

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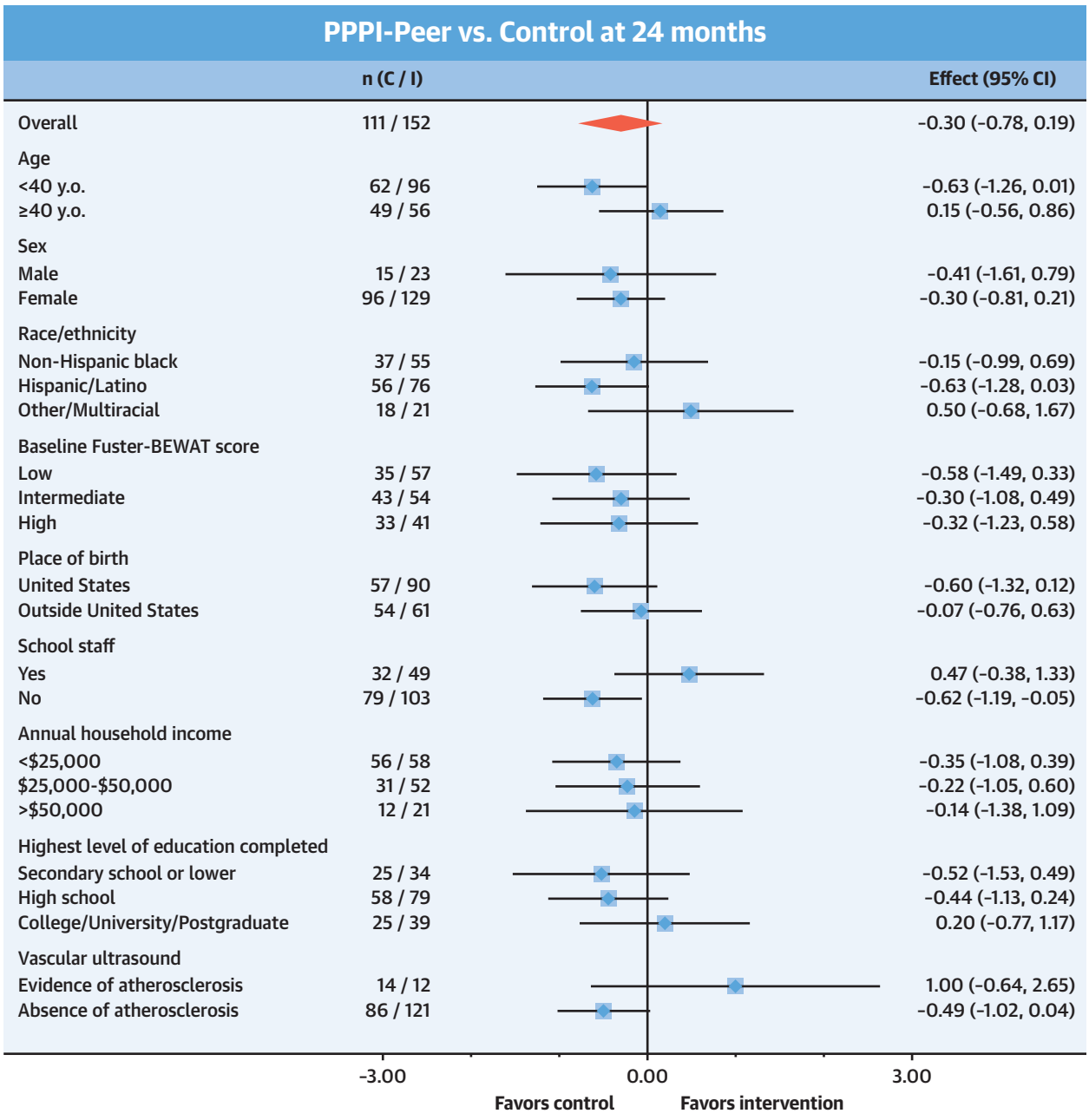
recent pragmatic randomized trial that enrolled 3,532 individuals aged 40 to 60 years with ≥1 conventional CV risk factors, in which the contributory role of pictorial presentation of silent atherosclerosis for the control of such risk factors was demonstrated (24). Although exploratory, the fact that the FAMILIA trial recruited a younger population at low risk for CV disease and with a low prevalence of (very early) atherosclerosis offers the potential for real impact on CV health promotion at the population level.

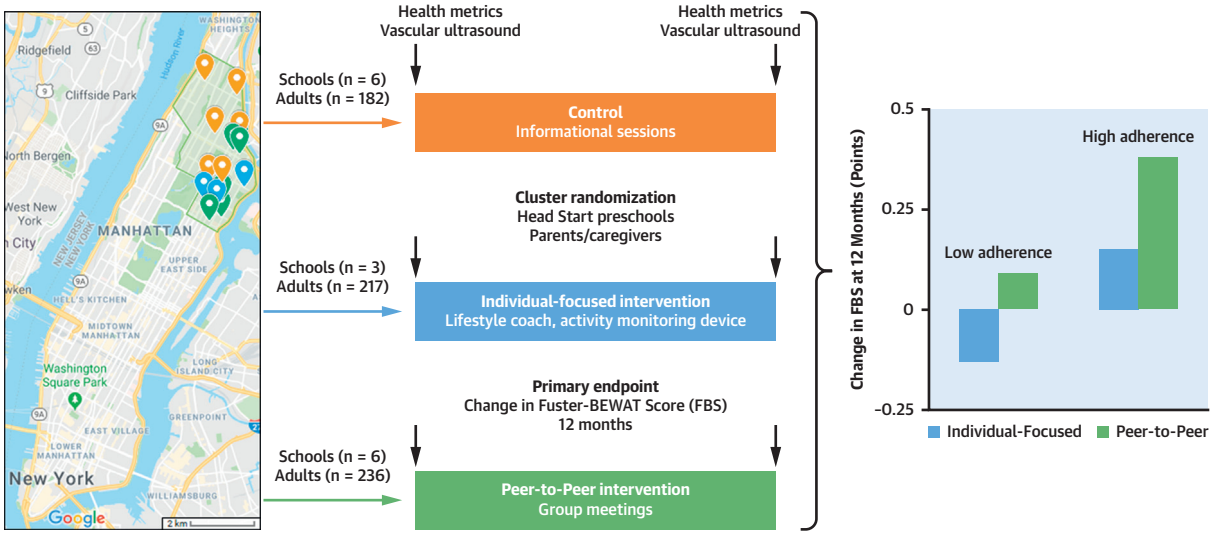
Yet speculative, the mechanisms of the higher intervention effect observed at 12 months in migrants

FIGURE 3 Continued



to the United States (as compared with participants born in the United States) might include positive health selection of migrants from originating countries, cultural differences in health-related behaviors, and supportive familial and social networks among migrants (25). We observed a greater impact of the intervention at 24 months in school staff as compared with parents or other family-related caregivers of the children. School staff are 1 of the cornerstones in children's behavior development, given that children spend a significant amount of time in school interacting with them (26). The particular impact of school staff motivation and health promotion programs targeted to school staff as means of positively affecting the lifestyle-related behavior of the children warrants future research.

CENTRAL ILLUSTRATION Effect of 2 Different Lifestyle Interventions in Underserved Communities



Fernandez-Jimenez, R. et al. J Am Coll Cardiol. 2020;75(1):42–56.

The FAMILIA (Family-Based Approach in a Minority Community Integrating Systems-Biology for Promotion of Health) trial enrolled 635 parents/caregivers of children attending preschools from an urban socioeconomically disadvantaged multiethnic community in New York City. Participants were randomized to intervention (individual-focused or peer-to-peer based lifestyle programs) for 12 months or control. The study did not show differences in the change of the nonlaboratory-based health Fuster-BEWAT score between control and intervention arms either at 12 months (immediate post-intervention) or at 24 months (sustainability). However, a dose-response relationship was observed with high-adherence participants exhibiting a significantly greater change. Furthermore, a potential contributory role of the presentation of atherosclerosis pictures was suggested.

STUDY STRENGTHS AND LIMITATIONS. Despite implementing intensive retention strategies over the course of the study, ~30% of participants were lost to follow-up at the primary endpoint assessment. This could have made the study underpowered to detect significant differences. Those completing the study were slightly older, were more frequently Hispanic/Latino and school staff, and had a relatively higher prevalence of atherosclerosis. Although we cannot completely exclude a significant impact of lost to follow-up participants on our results, complete-case intention-to-treat analyses were complemented with sensitivity analysis using multiple imputation procedures obtaining similar findings. A discussion on the acceptability of intervention programs and lessons learned is presented in the Online Discussion. Because recruitment was performed through schools and there were more female parents/caregivers present with their children at schools, the proportion of men enrolled in the FAMILIA trial was low. This is consistent with prior findings indicating that men, especially ethnic men, are under-represented in lifestyle weight loss trials (27).

One of the main strengths of the FAMILIA study is the cluster-randomized controlled design that allows isolation of the intervention effects. The low number of clusters in this study might lead to imbalances in effect estimates. As sensitivity analysis, we performed unadjusted cluster-level analysis obtaining similar results (no overall differences between groups in the change of FBS from baseline; data not shown). The main outcome measure was a nonlaboratory health score, i.e., FBS. Despite its simplicity, FBS performs similarly to other laboratory-based scores (11,28). These characteristics make the FBS particularly suited as a reliable low-cost indicator of CV health. Because of the low prevalence of atherosclerosis in the FAMILIA study, the possibility of evaluating the impact of lifestyle interventions on the progression of atherosclerosis was limited. Fidelity of the intervention was measured through individual attendance records which allowed us to evaluate a potential dose-response relationship. The fact that participants starting from a lower baseline score (among other subgroups) benefited more from the intervention could reflect a phenomenon of regression to the mean to a certain extent. Several strategies

were applied to alleviate this effect at the overall design (random allocation to comparison groups) and analysis (statistical models included adjustment for the baseline value of the outcome score) stages of the study. Nevertheless, results from subgroup analyses should be considered as exploratory. Despite the overall neutral effects, the study included the collection of adult blood material pre- and post-intervention. Samples will be analyzed in an effort to understand the complex relationships among lifestyle behavioral changes, atherosclerosis, and genomics (29).

CONCLUSIONS

Among parents/caregivers of children attending preschools from an urban multiethnic community enrolled in the FAMILIA trial, neither an intensive individual intervention program nor a peer-to-peer program intervention delivered over the course of 12 months demonstrated a significant impact on simple health metrics as compared with control subjects. A dose-response relationship was observed, indicating that intervention adherence is critical in achieving a potential beneficial impact. Furthermore, a contributory role of knowledge by the participant of the presence of atherosclerosis was suggested. This study provides helpful information to tailor and improve lifestyle interventions. A wider adoption of effective health promotion programs at the population level may have a meaningful impact on the reduction of health disparities and CV disease burden.

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PERSPECTIVES

COMPETENCY IN SYSTEMS-BASED PRACTICE: Effective health promotion is a global challenge. The FAMILIA trial identified no overall beneficial impact of a 12-month individual-focused or peer-based lifestyle intervention on health scores in an urban minority community. Adherence to the intervention was associated with greater efficacy, as was presenting pictures to a participant of his/her own atherosclerosis.

TRANSLATIONAL OUTLOOK: Further research is needed to identify factors that affect adherence to lifestyle interventions that improve cardiovascular health.

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KEY WORDS caregivers, health promotion, lifestyle, parents, vulnerable populations

APPENDIX For expanded Methods and Discussion sections as well as supplemental tables and figures, please see the online version of this paper.